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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,142	12/06/2006	Thomas Arendt	4121-180	5650

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/576,142	ARENDT ET AL.
	Examiner	Art Unit
	STACEY MACFARLANE	1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5 and 7-15* is/are pending in the application.

4a) Of the above claim(s) *9-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 7, 8, 14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 4, 5 and 8 have been amended, claims 14 and 15 newly added as requested in the amendment filed on March 23, 2011. Following the amendment, claims 1, 2, 4, 5, and 7-15 are pending in the instant application.

Claims 9-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Claims 1, 2, 4, 5, 7, 8 and 14-15 are under examination in the instant office action.

2. Applicant's arguments filed on March 23, 2011 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

3. As currently amended, Claims 8 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (35 U.S.C. 112, fourth paragraph), for reasons of record in the previous Office action mailed October 25, 2010. Claim 1 recites quantification by use of a CD69 antibody; however, claim 8 depends from claim 1 and adds quantifications by nucleic acid content. Therefore, claims 8 can be infringed by a method which does not infringe claim 1. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. See MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent

claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything, which would not also infringe the basic claim.

4. Additionally, Claim 8 is objected to because it starts with “Th method”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. As currently amended, Claim 1 is vague and indefinite for the following reasons. Steps (b) and (d) recite “the CD69”. It is unclear what this refers to: the CD69 surface marker protein, the CD69 gene, etc. One of ordinary skill would not know what the metes and bounds of the claim encompass.

9. As currently amended, Claim 4 still does not further limit the method of the parent claim. Rather, this claim recites an additional step with additional elements and it is unclear how these added elements relate back to the method for diagnosing Alzheimer’s disease, or when in the process they are to occur.

10. .Claim 8 recites the limitation "surface markers" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

11. As currently amended, Claim 14 is indefinite in that the preamble recites diagnosing patients suffering from AD but there is no resultant step relating the calculated stimulation index to said disease. It may be remedial to incorporate the limitation of Claim 15 into the method of Claim 14.

12. Claims 2, 5 and 7 are indefinite for depending from indefinite claims.

13. As currently amended, Claims 1, 2, 4, 5, 7, 8 and 14-15 stand as rejected under 35 U.S.C. 112, first paragraph, because the specification, for reasons of record in the previous Office action, as applied to claims 1, 2, 4, 5, 7 and 8. Briefly, while being enabling for a method of quantifying cells expressing the surface marker CD69, comprising obtaining a cell sample, quantifying cells within the sample expressing CD69, and optionally further comprising the steps of stimulating the cells by PHA or PWM, quantifying cells expressing the surface marker CD69, and calculating a stimulation index as the ratio of CD69 expression after mitogenic stimulation to unstimulated control, does not reasonably provide enablement for diagnosing Alzheimer's disease wherein the stimulation index of at least 10 with a reasonable expectation of success.

On pages 9-10 of Remarks filed March 23, 2011, Applicant traverses the rejection on the grounds that the claims as currently amended meet the enablement requirement, and that the subject matter of the claims is sufficiently supported by the specification and the Declaration of Dr. Arendt filed November 15, 2009.

While these arguments and evidence have been fully considered they are not persuasive to overcome the rejection for the following reasons. The scope of the instant claims is broadly drawn to diagnosing not only disease in those who have clinical manifestations of Alzheimer's disease, such as an MMSE score below 27, but in all subjects, based solely upon a stimulation index of greater than 10.

The Declaration of Dr. Arendt under 37 CFR 1.132 filed November 15, 2009 is insufficient to overcome the rejection of claims 1, 2, 4, 5, 7 and 8 based upon 35 U.S.C. 112, first paragraph as set forth in the last Office action because: The post-filing data does not provide a preponderance of evidence in support of any stimulation index above 10 being indicative of Alzheimer's disease pathology because: (a) the stimulation index formula found on page 3 of the Declaration appears to be different than that recited within the claim; and (b) the data on page 6 of the Declaration indicates that 4 of the control patients had a stimulation index of greater than 10. Additionally, the Steiler et al (2001) prior art, cited as reference AF on the IDS mailed September 5, 2006, teaches all of the method steps of the claims, but teaches a significantly **reduced stimulation index** after mitogen treatment (page 3971, Discussion. Therefore, it teaches away from the instant method wherein diagnosis is linked to an increased stimulation index of at least 10. Furthermore, as stated in the previous Office action, the experiments disclosed within the Declaration are correlated to MMSE scores of below 27 but the claims do not require this element. Thus, the experiments disclosed in the declaration do not correlate to what is claimed. Thus, taken together, the

preponderance of evidence teaches that the method as claimed is not enabled commensurate in scope with the breadth of the claims.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-R 5:45 to 3:30, TELEWORK-Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Salimi can be reached on (571) 272-0909. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/Lorraine Spector/
Primary Examiner, Art Unit 1647